



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,145	10/28/2003	Martin Gould	6149	6451
881	7590	11/17/2005	EXAMINER	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			YU, MELANIE J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,145

Applicant(s)

GOULD ET AL.

Examiner

Melanie Yu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-27 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed 22 August 2005 has been entered. Claims 1 and 14 are currently amended. Claims 26 and 27 are new. Claims 1-27 are currently pending in this application.

Withdrawn Rejections

2. Previous rejections under 35 USC 112, second paragraph have been withdrawn in light of applicant's arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "the mixture and second reagent combination" in line 9 of the claim. There is insufficient antecedent basis for this limitation in the claims.

4. Claim 14 recites "the mixture" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wickstead et al. (US 6,634,243) in view of Anderson et al. (US 6,267,722).

Wickstead et al. teach a lateral flow immunoassay device comprising: a housing (sample device; col. 4, line 41) including means for holding a test sample collector with a test sample contained within the collector (20, Fig. 1, sample collector; col. 4, lines 41-42); an elongated holder member securing at least one immunoassay test strip therein (test strip container; 50, Fig. 1; col. 4, line 42); a first chamber containing a first, pre-treatment reagent of a buffer (10, Fig. 1, buffer container; col. 4, line 41); a second chamber (second chamber contains filter, 30, Fig. 1, col. 4, line 42); a second reagent on the test strip (col. 7, lines 28-30); means for contacting the test sample with the pre-treatment reagent and allowing the test sample to mix with the first reagent to form a mixture (col. 9, lines 13-17); and means for allowing the mixture to contact at least one immunoassay test strip (37, Fig. 1, col. 5, lines 43-49). Wickstead et al. fail to teach a second reagent and means for introducing the second reagent to the mixture and allowing the mixture to react with the second reagent for a period of time prior to contacting the mixture and second reagent combination with at least one immunoassay strip.

Anderson et al. teach a prefilter containing a second reagent as an alternative to treating a test strip with a second reagent (conjugate pad, col. 32, line 60-col. 33, line 2); the conjugate pad providing a means for introducing a second reagent to a sample and allowing a sample to react with a second reagent for a period of time (col. 14, lines 7-15; col. 32, line 60-33, line 2) and means for allowing the sample and second reagent combination to contact an immunoassay test strip (col. 33, lines 3-8), in order to provide point of care diagnostic analysis system with rapid and accurate results.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the filter of the second chamber in the device of Wickstead

Art Unit: 1641

et al., a second chamber containing a filter comprising a second reagent as taught by Anderson et al., in order to enhance the diagnostic and risk assessment capabilities of decision-support methodologies in immunochromatographic assay systems. When the second reagents of Anderson et al. are placed on the filter instead of the test strip of Wickstead et al., a means for introducing a second reagent to a mixture of a first reagent and sample is provided. Furthermore, since the mixture flows from chamber 30 of Fig. 1 to the test strip, the second reagent is introduced prior to contacting the mixture and second reagent combination with the test strip. When the reagents of Wickstead et al. are in the filter instead of on the test strip the means for permitting the test sample, the test strip, the first reagent and the second reagent are in fluidic communication and the device comprises a means for permitting the test sample, the first reagent and second reagent to mix prior to contacting the mixture with a test strip.

Regarding claims 3-5 and 17-19, Anderson et al. teach the second reagent being disposed within a filter being a binder (labeled antibody conjugate; col. 32, line 60-col. 33, line 2) of a colloidal gold-antibody complex (col. 35, lines 22-23) or an antigen (col. 6, lines 53-56).

With respect to claims 6, 7, 10, 11, 15, 20, 22 and 23, Wickstead et al. teach the pretreatment reagent contained within a rupturable enclosure wherein the contacting means include a piercing membrane that ruptures the enclosure and releases the first reagent, and the test sample being in fluid communication with the first reagent when the test sample is released from the sample collector (col. 5, lines 14-26). Wickstead et al. further teach the contacting means including a button (110, Fig. 13) and a piercing member, wherein the button activates the piercing membrane to rupture the enclosure and release the first reagent contained therein (fluid-tight press fit between buffer container and sample collector, Fig. 13; col. 4, line 63-col. 5, line

Art Unit: 1641

6). Wickstead et al. also teach the holding means including an elongated slot (261 and 262, Fig. 16).

With respect to claims 8, 9 and 21, Wickstead et al. teach introducing means including apertures in communication with the second chamber through which the mixtures flows (filter, 230, Fig. 16; col. 5, lines 43-67) the mixture would contact the second reagent of Anderson et al. that is disposed within the filter (col. 32, line 60-col. 33, line 2). Wickstead et al. further teach the means for allowing the mixture to contact the at least one immunoassay test strip including the holding member being isolated so that at least one test strip does not contact the mixture until the mixture has reacted with the filter (col. 6, lines 64-65; col. 8, lines 33-36), which would cause the mixture to react with the second reagent disposed in the filter as taught by Anderson et al. before contacting the test strip (col. 32, line 60-col. 33, line 2).

Regarding claims 12, 13, 24 and 25, Wickstead et al. teach the housing being generally L-shaped (254, Fig. 16) with a vertical leg (lower part of device comprising parts 260, 261, 262) having a top and a bottom end (top end is toward the cap, 210, and bottom end is the lower part of the device in Fig. 16) and a horizontal leg extending outwardly from the bottom of the vertical leg (horizontal leg comprises parts 220 and 210 in Fig. 16 when fully assembled), wherein the test strip (240, Fig. 16) is located within the vertical leg (between 261 and 262 in Fig. 16).

5. With respect to claims 26 and 27, although Wickstead et al. fail to specifically teach the pre-treatment reagent diluting or denaturing interferants, such a limitation is drawn to an intended use and does not appear to further limit the structural limitations of the pre-treatment reagent. As described above, Wickstead et al. teach a buffer reagent which increases the test sample volume by mixing with the test sample and therefore dilutes interferants in a test sample.

Furthermore, since the buffer does not contain further interferants, the interferants of Wickstead are therefore diluted by mixing with the buffer.

Response to Arguments

6. Applicant's arguments regarding rejections under 35 USC 103(a) filed 31 August 2005 have been fully considered but they are not persuasive. Applicant argues that Wickstead does not relate to specific improvements which allow a sample to contact a first reagent in a first chamber combined with treatment with a second reagent in a second chamber. However as described above, the device of Wickstead allows a sample (sample in 20, Fig. 1) to contact with a first reagent (in 10, Fig. 1) before entering a second chamber comprising a filter. In response to applicant's argument that the reference fails to show the sample contacts a first reagent in a first chamber combined with treatment with a second chamber, it is noted that the features upon which applicant relies (i.e., the sample and first reagent contact in a first chamber) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further argues that the second compartment, which is interpreted as a chamber, of Wickstead (30, Fig. 1) merely provides a filter and not a chamber for providing a space wherein a second reagent and the first reagent can be retained to incubate the sample. However, the rejected claims do not specifically exclude a filter from the chamber and as taught by Anderson et al. a sample and second reagent are capable of mixing in a filter component comprising a second reagent (col. 14, lines 7-15).

Art Unit: 1641

7. Applicant argues that the device taught by Anderson et al. cannot be combined in any manner because there is no pre-treatment of the test sample using separate reagents which are mixed with the test sample prior to the time that the sample is contacted with the test strip, and the test sample is applied directly onto the test strip at which point the fluid communication begins without pre-treatment steps as provided by the present invention. However, Anderson et al. is not relied upon for these features. Anderson et al. is merely relied upon to provide motivation to include the second reagents found on the test strip of Wickstead et al. on the filter of Wickstead et al. in order to provide mixing of a sample and first reagent with a second reagent before application to a test strip. When the second reagents of Wickstead et al. are placed on the filter in the second chamber of Wickstead et al., the sample and first reagent mixture are mixed with a second reagent before application to a test strip. In response to applicant's argument that the Anderson fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., incubating and rapidly diluting a test sample before being applied to an immunoassay test strip) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, as discussed above, the buffer of Wickstead et al. dilutes interferants in the test sample because the buffer is not taught as containing interferants.

Conclusion

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


Art Unit: 1641


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Melanie Yu
Patent Examiner
Art Unit 1641


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
11/10/05